

## SUMMARY OF SAFETY AND EFFICACY

### A. Temperature

In a benchmark publication on temperatures which cause pulpal damage, Zach and Cohen showed that 15 % of teeth in dogs where pulpal temperature was raised to 10°F (5.5°C) had irreversible damage. These findings have been substantiated by Powell, et. Al. Therefore, if the pulpal temperature rises on only 5.5°C, one may conclude that there is no permanent damage to the pulp of the tooth due to the laser treatment.

**TABLE 1 - Pulp Temperatures**

Energy Output	Repetition Rate	Time with H2O Cooling	Temperature in °C
20 mJ	10 Hz	2 sec	.08°
50 mJ	10 Hz	2 sec	1.07°
100 mJ	10 Hz	2 sec	.84°
150 mJ	10 Hz	2 sec	1.12°
200 mJ	10 Hz	2 sec	2.3°
Drill in Air	not applicable	10 sec	.25°
Drill in H2O	not applicable	10 sec	.05°

### B. Pulp Vitality (all blinded):

1. H&E histological evidence over pulpal healing time demonstrates no deleterious effect for laser or control treatment.
2. Pulp vitality measurements over 1½ year follow-up demonstrate no compromise in pulp vitality.
3. Pulp vitality measurements on two teeth in each of 33 patients treated by laser and drill from the same patient show no difference in pulpal vitality pre-surgery, post-surgery and over three months.
4. Pulp vitality measurements on 125 randomly treated adult teeth treated by laser and drill show no significant difference between the laser and the control in pulp vitality measurements pre-surgery and after a three month period.

**C. Surface Morphology (all blinded):**

1. Animal and human studies using SEM demonstrated no changes in surface morphology except at the treatment site.
2. Animal and human studies using SEM illustrated that the drill and laser show equivalent surface changes at the treatment site.

**D. Structural Morphology**

1. The ideal etched tooth presents a roughened dentin or enamel surface and no evidence of cracking, fissuring or charring. The dentin demonstrates open dentinal tubules. Organic material has been vaporized leaving the inorganic components of the tooth - leaving greater tooth surface area. In addition, a cavity preparation should show no remaining evidence of caries and a crater created by removal of tooth structure below the margin of the preparation.
2. Hibst and Keller reported on the effective removal of tooth structure with ultrastructural changes in enamel and dentin. There were no fissures or cracks. The surface was scaled and roughened without signs of thermal damage. Laser dosimetries ranged from 50 - 350 mJ.
3. Paghdiwala showed at 430 mJ, hydroxyapatite has vaporized, developing pores and surrounded by elevated fused inorganic tissue. No visible cracks radiated from the craters.

**E. Adjacent Structures**

1. Adjacent structures to the treated tooth surface include soft tissue, proximal teeth and underlying bone. The damage due to inadvertent lasing of adjacent structures is usually less than the drill, since the laser does not cut effectively when defocused.

**F. Efficacy**

1. Investigators rate caries removal more effective than the drill.
2. Investigators rate cavity preparation with the laser equal to the drill.
3. Investigators rate laser etching much more effective than acid etching.
4. Animal and human studies demonstrate that the Er:YAG laser is equivalent to standard treatment.

5. In a multi-site study of 125 randomized human adult teeth, all classes of caries (I-V) were completely removed in 100% of the teeth treated.
6. In a multi-site study of 125 randomized human adult teeth all cavity preparation and restoration was still adequate after 3 months in 100% of treated teeth.

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